no persons are required to respond to a collection of infor

REQUEST FOR ACCESS TO AN ABANDONED APPLICATION UNDER 37 CFR 1.14

Bring completed form to: File Information Unit Crystal Plaza Three, Room 1001 2021 South Clark Place Arlington, VA

Telephone: (703) 308-2733

RECEIVED

SEP 0 1 2006

File Information Unit

In re Application of Application Number

I hereby request access under 37 CFR 1.14(a)(1)(iv) to the application file record of the above-identified ABANDONED application, which is identified in, or to which a benefit is claimed, in the following document (as shown in the attachment):

United States Patent Application P	ublication No		page,	_ line
United States Patent Number 66	015567	column	, line,	or
WIPO Pub. No	, page	, line		

Related Information about Access to Pending Applications (37 CFR 1.14):

Direct access to pending applications is not available to the public but copies may be available and may be purchased from the Office of Public Records upon payment of the appropriate fee (37 CFR 1.19(b)), as follows: For published applications that are still pending, a member of the public may obtain a copy of:

the file contents:

the pending application as originally filed; or any document in the file of the pending application.

For unpublished apolications that are still pending:

(1) If the benefit of the pending application is claimed under 35 U.S.C. 119(e), 120, 121, or 365 in another application that has: (a) issued as a U.S. patent, or (b) published as a statutory invention registration, a U.S. patent application publication, or an international patent application publication in accordance with PCT

Article 21(2), a member of the public may obtain a copy of:

the file contents;

the pending application as originally filed; or

any document in the file of the pending application.

(2) If the application is incorporated by reference or otherwise identified in a U.S. patent, a statutory invention registration, a U.S. patent application publication, or an international patent application publication in accordance with PCT Article 21(2), a member of the public may obtain a copy of:

the pending application as originally filed.

Registration Number, if applicable

Telephone Number

103-553 0006

09-01-06

File Information Unit

This collection of information is required by 37 CFR 1.14. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the including the completed application form to the USPTO. Time will vary depending upon the included case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer. U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. BRING TO: File Information Unit, Crystal Plaza Three, Room 1001, 2021 South Clark Place, Arlington, VA.



United States Patent [19]

Hudziak et al.

[11] **Patent Number:**

6,015,567

Date of Patent: [45]

Jan. 18, 2000

[54] HER2 EXTRACELLULAR DOMAIN

[75] Inventors: Robert Michael Hudziak, San Bruno;

H. Michael Shepard, San Francisco, both of Calif.; Axel Ullrich,

Martinsried, Germany

[73] Assignee: Genentech, Inc., South San Franisco,

Calif.

[21] Appl. No.: 08/422,108

[22] Filed: Apr. 14, 1995

Related U.S. Application Data

1621	Division of application No. 08/355,460, Dec. 13, 1994,
. ,	abandoned, which is a continuation of application No.
	08/048,346, Apr. 15, 1993, abandoned, which is a continu-
	ation of application No. 07/354,319, May 19, 1989, aban-
	doned.

[51] Int. Cl.⁷ A61K 38/00; C07K 14/705; C07K 19/00

...... 424/277.1; 424/185.1; 424/192.1; 424/278.1; 424/282.2; 530/402;

530/403 [58] Field of Search 424/185.1, 192.1, 424/278.1, 277.1, 282.2; 530/402, 403

[56] References Cited

U.S. PATENT DOCUMENTS

8/1988 Bell et al. . 4,761,371 4,877,611 10/1989 Cantrell . 4,935,341 6/1990 Bargmann et al. . 4,963,354 10/1990 Shepard. 11/1990 Slamon . 4,968,603 5,030,576 7/1991 Dull et al. 5,081,228 1/1992 Dower et al. 5,126,433 6/1992 Maddon et al. . 5,183,884 2/1993 Kraus et al. . 5,401,638 3/1995 Carney et al. .

FOREIGN PATENT DOCUMENTS

WO 89/01973 3/1989 WIPO. WO 89/06692 7/1989 WIPO. WO 89/10412 11/1989 WIPO. WO 91/02062 2/1991 WIPO.

OTHER PUBLICATIONS

Yamamoto et al Nature 119: 230-234 1986. Derbin PNAS 83 9129-9133 1986. Mitchell et Al Cancer Res 48: 5883-5893 1988. Hoover et al Cancer 55: 1236-1243 1985. Capon et al Nature 337: 525-531 1989. Tal et al Cancer Res. 48: 1517-1520 1988. Zhou et al Cancer Res. 47: 6123-6125 1987. Bernards et al PNAS 84: 6854-6858 1987. Ezell, C J. of NIH Research 7: 46-49 1995. Akiyama et al., "The product of the human c-erbB-2 Gene:

a 185-Kilodalton Glycoprotein with tyrosine Kinase Activity" Science 232:1644-1646 (1986).

Bargmann et al., "The neu oncogene encodes an epidermal growth factor receptor-related protein" Nature 319:226-230 (1986).

Bernards et al., "Effective tumor immunotherapy directed against an oncogene-encoded product using a vaccinia virus vector" Proc. Natl. Acad. Sci. USA 84:6854-6858 (1987). Coussens et al., "Tyrosine Kinase Receptor with Extensive Homology to EGF Receptor Shares Chromosomal Location with neu Oncogene" Science 230:1132-1139 (1985).

Drebin et al., "Down-Modulation of an Oncogene Protein Product an Reversion of the Transformed Phenotype by Monoclonal Antobodies" Cell 41(3):695-706 (1985).

Drebin et al., "Inhibition of tumor growth by a monoclonal antibody reactive with an oncogene-encoded tumor antigen" Proc. Natl. Acad. Sci. 83:9129-9133 (1986).

Drebin et al., "Monoclonal antibodies reactive with distinct domains of the neu oncogene-encoded p185 molecule exert synergistic anti-tumor effects in vivo" Oncogene 2:273-277 (1988).

Drebin et al., "Monoclonal antibodies specific for the neu oncogene product directly mediate anti-tumor effects in vivo" Oncogene 2(4):387-394 (1988).

Fendly et al., "The Extracellular Domain of HER2/neu Is a Potential Immunogen for Active Specific Immunotherapy of Breast Cancer" Journal of Biological Response Modifiers 9:449-455 (1990).

Fendly et al., "Successful Immunization of Rhesus Monkeys with Extracellular Domain of p185HER2: A Potential Approach to Human Breast Cancer' Vaccine Research 2(3):129-139 (1993).

Graham et al., "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA" Virology 52:456-467 (1973).

Hopp et al., "Prediction of protein antigenic determinants from amino acid sequences" Proc. Natl. Acad. Sci. USA 78(6):3824-3828 (1981).

Hudziak et al., "Amplified Expression of the HER2/ERBB2 Oncogene Induces Resistance to Tumor Necrosis Factor a in NIH 3T3 Cells" Proc. Natl. Acad. Sci. USA 85:5102-5106 (1988).

Hudziak et al., "Increased expression of the putative growth factor receptor p185^{HER2} causes transformation and tumorigenesis of NIH 3T3 cells" Proc. Natl. Acad. Sci. 84:7159-7163 (1987).

Hudziak et al., "p185HER2 Monoclonal Antibody Has Antiproliferative Effects In Vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor" Molecular & Cellular Biology 9(3):1165-1172 (1989).

Kane et al., "Formation of recombinant protein inclusion bodies in Escherichia coli" Tibtech 6:95-101 (1988).

(List continued on next page.)

Primary Examiner-Thomas M. Cunningham Assistant Examiner-Martha Lubet Attorney, Agent, or Firm-Wendy M. Lee

ABSTRACT [57]

A method of treating a human patient via active immunotherapy comprising administrating an effective amount of extracellular portion of human HER2 receptor to the patient wherein the method provokes a cell-mediated immune response to HER2 receptor in the patient treated therewith.

26 Claims, 13 Drawing Sheets